510(k) Summary

MAY 2 1 2007

Trinity Orthopedics, LLC
Single Planar Multi Axial (SPMA) Pedicle Screw System

ADMINISTRATIVE INFORMATION

Manufacturer Name: Trinity Orthopedics, LLC
8817 Production Avenue
San Diego, CA 92121
Telephone 1 (858) 689-4113
Fax 1 (858) 689-4115

Official Contact: James F. Marino, M.D.

Representative/Consultant: Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone 1 (858) 792-1235
Fax 1 (858) 792-1236
email: flarson@paxmed.com

DEVICE NAME

Classification Name: Pedicle Screw Spinal System
Trade/Proprietary Name: SPMA Pedicle Screw System
Common Name: Pedicle Screw System

DEVICE CLASSIFICATION

FDA has classified "Pedicle Screw Spinal System" as Class II devices (21 CFR 888.3070), with a product codes of MNI and MNH.

INTENDED USE

The Single Planar Multi Axial (SPMA) Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, spinal stenosis, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis, and failed previous fusion.

DEVICE DESCRIPTION

The SPMA Pedicle Screw System is an internal fixation device for spinal surgery consisting of rods and pedicle screw assemblies (screw, saddle, axle, locking washer and set screw). The axle that connects the screw to the saddle allows the saddle to be adjusted in a single plane to any angle, up to 60 ° from the midline. Grooves in the head of the screw and in the inferior face of the locking washer interdigitate with the splined surface of the rod to allow the assembly to be rigidly fixed in place when tightened.

Component Description

Rod

SPMA Pedicle Screw System rods are 6.0 mm diameter solid splined cylinders which are provided non-contoured and pre-contoured to accommodate the lordotic curve. Pre-contoured rods and standard non-contoured rods are available in a variety of lengths. The rods fit into the pedicle screw saddle of the pedicle screw assembly. After the rods are placed in the pedicle screw saddle, the locking washer and set screw are secured to the pedicle screw. The rods are provided in titanium alloy and Co-Cr-Mo alloy.

Pedicle Screw Assembly

Each SPMA pedicle screw assembly consists of a cannulated titanium alloy screw with a proximal articulating saddle held in place with a transverse axle. The axle joining the mating surfaces of the screw and saddle allows for up to 60° angulation from midline in a single plane.

The locking washer is placed atop the rod within the saddle and held in place with the set screw. The grooved design of the locking washer and the proximal end of the screw allow for close interdigitation with the splined surface of the rod, fixing the angle of the saddle.

Additional Components

A series of manual surgical instruments (not subject of this submission) intended to assist the insertion and placement of the implants (pedicle screws, rods, set screws, and locking washers) is included in an instrument tray.

PERFORMANCE TESTING

Mechanical testing performed on the SPMA Pedicle Screw System using titanium rods demonstrated equivalence of the device to legally marketed predicate devices.

EQUIVALENCE TO MARKETED PRODUCT

Trinity Orthopedics, LLC submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the SPMA Pedicle Screw System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: OPTIMA™ Spinal System (K051971) from U & I Corporation, the MOSS® Miami Spinal System (K955348, K982511, K983583, K022623) from DePuy AcroMed, Inc., the Stryker Xia® Spinal System (K001272, K043473, K060979, K063428) from Stryker Spine, and the CD HORIZON® Spinal System (K961633, K001255) from Medtronic Sofamor Danek, Inc.

The SPMA Pedicle Screw System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design, and
- incorporates the same materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trinity Orthopedics, LLC
% Mr. Floyd G. Larson
Paxmed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

MAY 2 1 2007

Re: K070295
Trade/Device Name: Single Planar Multi Axial (SPMA) Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: April 25, 2007
Received: April 27, 2007

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehler
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Indications for Use

Applicant: Trinity Orthopedics, LLC

510(k) Number (if known): K070295

Device Name: Single Planar Multi Axial Pedicle Screw System

Indications for Use:

The Single Planar Multi Axial (SPMA) Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, spinal stenosis, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070295